

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

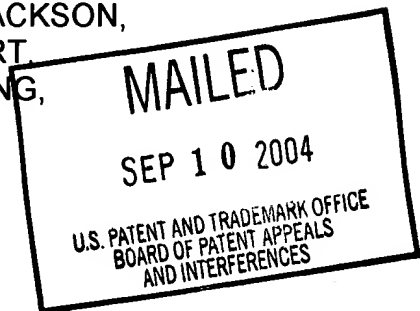
Ex parte RAAFAT E.F. FAHIM, GAIL E.D. JACKSON,
LARRY U.L. TAN, ANDREW HERBERT,
LUIS BARRETO, JOHN THIPPHAWONG,
LESLIE BOUX, JOHN R. VOSE
and MICHEL H. KLEIN

Appeal No. 2001-2180
Application No. 08/501,743

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and LORIN, Administrative Patent Judges.

LORIN, Administrative Patent Judge.



This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 27-39 and 42, all the claims pending in the application.¹

¹ Pursuant to 35 U.S.C. § 6(b), we review the adverse decision of the examiner. In doing so, we have considered the record, including:

- Final Rejection (Paper no. 11);
- Brief (Paper no. 13);
- Amended Brief (Paper No. 17); and
- Examiner's Answer (paper no. 27).

Claims 27 and 42 are illustrative of the claims on appeal. They read as follows:

27. A vaccine composition for protecting an at-risk human population against a case of the disease (whooping cough) caused by infection by B. pertussis, which comprises pertussis toxoid, filamentous haemagglutinin, pertactin and agglutinogens of B. pertussis, all in purified form, in selected relative amounts to confer protection to the extent of at least about 70% of members of the at-risk population.

42. A method of immunizing an at-risk human population against disease caused by infection by B. pertussis, which comprises administering to members of the at-risk human population an immunoeffective amount of the vaccine composition of claim 27 to confer protection to the extent of at least about 70% of the members of the at-risk population.

The reference relied upon by the examiner is:

Englund et al. (Englund), "Controlled Study of a New Five-Component Acellular Pertussis Vaccine in Adults and Young Children," Journal of Infectious Diseases, Vol. 166, pp. 1436-1441 (1992).

The rejections are:

1. Claims 27-29, 31-34, 38, 39 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Englund.
2. Claims 27-39 and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Englund.

DISCUSSION

As a preliminary matter, we note that two briefs have been filed. The latter brief, the "Amended Appeal Brief" (Paper No. 17), is the one we will rely upon.

Claims 27-39 and 42 do not stand or fall together (see Answer, p. 3 and Brief, p.

3). Consistent with appellants' amended brief, we will address each claim individually.

To facilitate comparing the claimed subject matter and the Englund disclosure, we include a chart showing the compositions set forth in each vaccine claim and the corresponding teaching of Englund.

INDEPENDENT CLAIM	27	27	27	27	27	27	27	27	27	27	27	27	27	Englund
DEPENDENT CLAIM		28	28	28	31	32	32	34	34	36	36	38	38	
SUBDEPENDENT CLAIM			29	30			33		35		37		39	
pertussis toxoid	>0	5-30	10	20	>0	>0	>0	>0	>0	>0	>0	>0	>0	10
FHA	>0	5-30	5	20	>0	>0	>0	>0	>0	>0	>0	>0	>0	5
pertactin	>0	3-15	5	5	>0	>0	>0	>0	>0	>0	>0	>0	>0	3
agglutinogens	>0	1-10	3	3	>0	>0	>0	>0	>0	>0	>0	>0	>0	5
Agg2:Agg3	n/a	n/a	n/a	n/a	n/a	n/a	n/a	>0:>0 no Agg1	1.5:1 - 2:1	n/a	n/a	n/a	n/a	>0:>0 no Agg1
tetanus toxoid	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	>0	5	n/a	n/a	5
diphtheria toxoid	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	>0	15	n/a	n/a	15
adjuvant	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	>0	>0	>0
alum	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	>0	>0
protection	>70%	>70%	>70%	>70%	>80%	>70%	>80%	>70%	>70%	>70%	>70%	>70%	>70%	n/a

Claim 27²

Claim 27 stands rejected over Englund under both §§ 102 and 103.

In a nutshell, the examiner takes the position that Englund teaches the claimed vaccine. That is the case. Englund teaches all the components in the claimed vaccine and teaches amounts that fall squarely within the broad ranges claimed.

The dispute is only over the significance of the following phrase in the claim: "to confer protection to the extent of at least about 70% of members of the at-risk

² 27. A vaccine composition for protecting an at-risk human population against a case of the disease (whooping cough) caused by infection by *B. pertussis*, which comprises pertussis toxoid, filamentous haemagglutinin, pertactin and agglutinogens of *B. pertussis*, all in purified form, in selected relative amounts to confer protection to the extent of at least about 70% of members of the at-risk population.

population.” Given that all the components and amounts are taught by Englund, it follows that Englund’s composition would have the same property. Notwithstanding that Englund does not disclose the extent of the protection that its vaccine would confer, claiming of a unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Appellants have not pointed to any difference between the composition claimed and that of Englund. Accordingly, the protection described in the claim does not distinguish the claimed vaccine from Englund.

The rejections under §§ 102 and 103 are AFFIRMED.

Claim 28³

Claim 28 stands rejected over Englund under both §§ 102 and 103.

Claim 28 distinguishes from Claim 27 in narrowing the range of amounts for the five major components of the vaccine. However, these more narrow ranges nevertheless still encompass the amounts in Englund (see the chart supra). Otherwise the claimed vaccine is no different from that presented in claim 27. Accordingly, we reach the same conclusion.

The rejections under §§ 102 and 103 are AFFIRMED.

³ 28. The vaccine of claim 27 wherein said pertussis toxoid is present in an amount of about 5 to about 30 µg nitrogen, said filamentous haemagglutinin is present in an amount of about 5 to about 30 µg nitrogen, said pertactin is present of about 3 to about 15 µg nitrogen and said agglutinogens are present in an amount of about 1 to about 10 µg nitrogen, in a single human dose.

Claim 29⁴

This claim narrows the composition to read as follows:

- Pertussis toxoid: 10 µg;
- FHA: 5 µg;
- Pertactin: 5 µg; and,
- Agglutinogens: 3 µg.

Claim 29 stands rejected over Englund under both §§ 102 and 103.

Examiner's position is that the composition is identical to Englund's. Appellants concede as much: "the Englund et al reference describes a five-component acellular pertussis composition which is formulated according to claim 29 in respect of the individual pertussis components (Amended Brief, p. 5).

However, our reading of Englund reveals the composition to be as follows:

- Pertussis toxoid: 10 µg;
- FHA: 5 µg;
- Pertactin: 3 µg; and,
- Agglutinogens: 5 µg.

They are not the same.

Given the lack of identity, we REVERSE the rejection under §102.

Regarding the 103 rejection, we can find nothing in Englund, and the examiner does not point to anything therein, that would lead one to change the composition of the vaccine taught therein to the one claimed. Englund teaches but one composition and

⁴ 29. The vaccine of claim 28 containing 10 µg nitrogen of pertussis toxoid, about 5 µg nitrogen of filamentous haemagglutinin, about 5 µg nitrogen of pertactin and about 3 µg nitrogen of agglutinogens in a single human dose.

makes no statement that would lead one to consider changing it. Examiner has not presented a prima facie case of obviousness and the rejection is REVERSED.

Claim 30⁵

This claim, like claim 29, specifies a specific composition for the vaccine. Similarly, this composition is not taught in Englund. This claim is rejected only under §103 but, because the examiner has not shown how Englund would suggest modifying the single composition it teaches to the one claimed, the rejection is REVERSED.

Claims 31⁶, 32⁷, 33⁸

These claims further describe properties associated with the composition of Claim 27. They are rejected under §§ 102 and 103.

We repeat our view stated in our discussion of the rejections of claim 27. Given that all the components and amounts are taught by Englund, it follows that Englund's composition would have the same property. Appellants have not pointed to any

⁵ 30. The vaccine of claim 28 containing 20 µg nitrogen of pertussis toxoid, about 20 µg nitrogen of filamentous haemagglutinin, about 5 µg nitrogen of pertactin and about 3 µg nitrogen of agglutinogens in a single human dose.

⁶ 31. The vaccine of claim 27 wherein the extent of protection is at least about 80% for a case of pertussis having a cough of at least one day duration.

⁷ 32. The vaccine of claim 27 wherein the extent of protection is at least about 70% for a case of mild pertussis having a cough of at least one day duration.

⁸ 33. The vaccine of claim 28 wherein the extent of protection is about 85% for a case having a spasmodic cough of duration at least 21 days and confirmed bacterial infection.

difference between the composition claimed and that of Englund. Accordingly, the protections described in these claims do not distinguish them from Englund.

The rejections under §§ 102 and 103 are AFFIRMED.

Claim 34⁹

This claim further defines the vaccine composition of claim 27 as including agglutinogens 2 and 3 only. Englund teaches this (p. 1436, near the bottom of the second column). Accordingly, the rejections under §§ 102 and 103 of this claim over Englund are AFFIRMED.

Claim 35¹⁰

This claim further defines the vaccine composition of claim 33 by providing specific ranges for amounts for agglutinogens 2 and 3. Englund does not teach this. Moreover, examiner does not point to anything in Englund that would suggest to one of ordinary skill to formulate a vaccine composition with amounts of agglutinogens 2 and 3 in the ranges claims. Accordingly, the rejection under § 103 of this claim over Englund is REVERSED.

⁹ 34. The vaccine of claim 27 wherein said agglutinin comprise fimbrial agglutinin 2 (Agg 2) and fimbrial agglutinin 3 (Agg 3) substantially free from agglutinin 1.

¹⁰ 35. The vaccine of claim 34 wherein the weight ratio of Agg 2 to Agg 3 is from about 1.5:1 to about 2:1.

Claims 36¹¹ and 37¹²

Claims 36 and 37 further define the vaccine composition as including tetanus toxoid and diphtheria toxoid. This is clearly taught in Englund (see p. 1437, top paragraph of first column) as are the amounts specified by Claim 37. Englund anticipates these claims. Although these claims are rejected under §103 only, they are AFFIRMED since anticipation is the epitome of obviousness.

Claims 38¹³ and 39¹⁴

Claims 38 and 39 further define the vaccine composition as including an adjuvant and the adjuvant being alum, respectively. This is clearly taught in Englund (see p. 1437, second full paragraph of first column).

These claims are rejected under §§ 102 and 103. They are AFFIRMED.

Claim 42¹⁵

Unlike the other claims, Claim 42 is a process claim.

¹¹ 36. The vaccine of claim 27 further comprising tetanus toxoid and diphtheria toxoid.

¹² 37. The vaccine of claim 36 wherein said diphtheria toxoid is present in an amount of about 15 Lfs and tetanus toxoid is present in an amount of about 5 Lfs.

¹³ 38. The vaccine of claim 27 further comprising an adjuvant.

¹⁴ 39. The vaccine of claim 38 wherein the adjuvant is alum.

¹⁵ 42. A method of immunizing an at-risk human population against disease caused by infection by B. pertussis, which comprises administering to members of the at-risk human population an immunoeffective amount of the vaccine composition of claim 27 to confer protection to the extent of at least about 70% of the members of the at-risk population.

Englund teaches a process of administering to members of the at-risk human population an immunoeffective amount of the vaccine composition of claim 27. This is shown in the studies discussed at pages 1438-1440. There appears to be no dispute about that. The only question, again, is whether Englund's process "[confers] protection to the extent of at least about 70% of members of the at-risk population." Given that all the components and amounts and step of administering are taught in Englund, it follows that Englund's process confers the same property. Notwithstanding that Englund does not disclose the extent of the protection that its vaccine would confer, claiming of a unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Appellants have not pointed to any difference between the process claimed and that of Englund. Accordingly, the protection described in the claim does not distinguish the claimed process from Englund.

The rejections under §§ 102 and 103 are AFFIRMED.

CONCLUSION

The rejections under §§ 102 and 103 over Englund of the following claims are AFFIRMED: 27, 28, 31-34, 38, 39 and 42.

The rejections under §103 over Englund of the following claims are AFFIRMED: 36 and 37.

The rejection under §§ 102 and 103 over Englund of the following claims are

The rejection under § 103 over Englund of the following claim is REVERSED:

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

Sherman D. Winters
SHERMAN D. WINTERS

WILLIAM F. SMITH


HUBERT C. LORIN

HUBERT C. LORIN
Administrative Patent Judge

APPEALS AND

INTERFERENCES

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